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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,667	10/27/2003	Paul J. Maddon	P0741.70006US00	4456

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12/10/2008

PROGENICS PHARMACEUTICALS, INC.

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BOSTON, MA 02210-2206

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,667

Applicant(s)

MADDON ET AL.

Examiner

Stephen L. Rawlings

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48, 51-53, 55, 56, 59-61, 63-90 and 187-265 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 48, 51-53, 55, 56, 59-61, 63-90 and 187-265 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed August 20, 2007, is acknowledged and has been entered. Claims 1-47, 49, 50, 54, 57, 58, 62, 91-101, and 169-186 have been canceled. Claims 48, 51-53, 55, 59, 60, 61, 63, 64, 71, 73, 76, 78, 79, 187, 188, and 190-193 have been amended. Claims 194-265 have been added.
2. The amendment filed August 22, 2008, is acknowledged and has been entered. Claim 78 has been amended.
3. Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-265 are pending in the application and subject to the following restriction and election requirement.

Election/Restrictions

4. This application contains claims directed to the patentably distinct species of the elected species of invention.

(a) As originally presented for prosecution on the merits the claims were directed to a composition comprising isolated PSMA protein, wherein a percentage of the protein is multimeric, or more particularly dimeric, wherein the dimer comprises a fragment of a full-length PSMA molecule, or more particularly a fragment of the extracellular portion of PSMA, and wherein said fragment comprises amino acids 58-750 of SEQ ID NO: 1, amino acids 44-750 of SEQ ID NO: 1, or amino acids 601-750 of SEQ ID NO: 1.

As amended, generic claims 48, 51-53, 55, 56, 59-61, 63-90, 187-195, 200-233, and 238-260 are now directed to a plurality of newly presented species of the invention, wherein said composition comprises a dimer of PSMA proteins, wherein the sequence of each PSMA protein of said dimer comprises the sequence set forth as SEQ ID NO: 1 or a portion thereof selected from the group consisting of the sequence of amino acids

44-750 of SEQ ID NO: 1, the sequence of amino acids 58-750 of SEQ ID NO: 1, and the sequence of amino acids 601-750 of SEQ ID NO: 1.

Though perhaps subtle, there is a significant distinction made between the subject matter to which the originally presented claims were directed and the subject matter to which the amended claims are directed.

Whereas the originally presented claims were directed to a dimer comprising a *fragment of the extracellular portion of PSMA*, or more particularly a fragment of the extracellular portion of PSMA comprising amino acids 58-750 of SEQ ID NO: 1, amino acids 44-750 of SEQ ID NO: 1, or amino acids 601-750 of SEQ ID NO: 1, the amended claims are directed to a dimer comprising a PSMA protein, and not necessarily a fragment of the extracellular portion of PSMA, which comprises the sequence of amino acids 44-750 of SEQ ID NO: 1, the sequence of amino acids 58-750 of SEQ ID NO: 1, and the sequence of amino acids 601-750 of SEQ ID NO: 1.

In effect, although inclusive of some of the same embodiments encompassed by the originally presented claims, such as a composition comprising a dimer comprising full-length PSMA molecules, the amended claims are directed to broader subject matter than were the originally presented claims.

Due to such distinctions, it would be a serious burden to now have to consider the merit of the amended claims, were Applicant not now required to elect a single species of invention.

This is because the search and considerations made in the first action on the merits will not suffice to examine claims directed to the newly presented species of invention.

Furthermore, it is submitted that each of the different species of invention is patentably distinct from the others.

While examination of claims directed to each of the different species of invention might require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries), it is more aptly noted that prior art applicable to one species would not likely be applicable to another subspecies.

Furthermore, consideration of claims directed to different species of invention is likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or 35 U.S.C. § 112, first paragraph, which were not raised by the originally presented claims.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of invention for prosecution on the merits to which the claims shall be restricted, if no generic claim is finally held to be allowable.

Applicant should do so by specifying the portion of SEQ ID NO: 1 of which the "PSMA protein" to which the claims are directed shall be comprised. Accordingly, Applicant should select one of the following portions of SEQ ID NO: 1: (a) the sequence of amino acids 44-750 of SEQ ID NO: 1, (b) the sequence of amino acids 58-750, and (c) the sequence of amino acids 601-750.

The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, *but* not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

(b) Turning to another issue now, the originally presented claims were directed to a composition comprising a solution having a pH ranging from 4 to 8, from 5 to 7, or from 5.5 to 7, or more particularly having a pH of 6; and in contrast, the amended claims are directed to a composition comprising a solution having a pH in the range of 6 to 7.5, or more particularly a pH selected from the group consisting of a pH of 7.5, a pH of 7, and a pH of 6.5.

Due to such distinctions, it would be a serious burden to now have to consider the merit of the amended claims, were Applicant not now required to elect a single species of invention.

This is because the search and considerations made in the first action on the merits will not suffice to examine claims directed to the newly presented species of invention.

The different species of invention are presumably not obvious variants of each other, at least not based on the current record.

As such, it appears that each of the different species of invention is patentably distinct from the others.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of invention for prosecution on the merits to which the claims shall be restricted, if no generic claim is finally held to be allowable.

Applicant should do so by specifying the pH of the solution of which the composition is comprised; the pH should be selected from the group consisting of a pH of 7.5, a pH of 7, and a pH of 6.5.

Again, the Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, *but* not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

5. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the subspecies may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of subspecies requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected subspecies.

Should applicant traverse on the ground that the subspecies are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or *clearly* admit on the record that this is the

case. In either instance, if the examiner finds one of the subspecies unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other subspecies.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional subspecies which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

slr
December 7, 2008